

[CryoGen-1]

**METHODS AND APPARATUS FOR APPLYING A THERMAL CONDUCTIVE
MEDIUM**

FIELD OF THE INVENTION

5 The present invention is directed to methods
and apparatus for coating the inside of at least a
portion of a sheath, e.g., a sheath used to cover a
medical device, with a thermal conductive medium (TCM).

BACKGROUND OF THE INVENTION

10

Medical devices, e.g., probes, are used in a
variety of applications. Such probes are frequently
inserted into the human body as part of medical
15 procedure. Probes are often relatively expensive durable
devices. In many cases, absent the risk of disease
transfer and/or infection, probes may be used repeatedly.
Unfortunately, a probe's shape and/or construction can
make it difficult to sterilize thoroughly between uses.

20

For purposes of avoiding infection and the
problems associated with sterilizing a probe thoroughly a
sterile sheath may be used to cover the portion of the
probe which is inserted into the human body. After each
25 use, the used sheath is discarded and replaced with a new
sterile sheath thereby allowing reuse of the probe at a
minimal cost.

In cases of medical probes where thermal conductivity is important, e.g., cryogenic probes and/or temperature sensing probes, the sheath should not
5 interfere significantly with the transfer of heat to/from portions of the probe where thermal transfer is intended to occur.

One example of a medical probe that may use a
10 sheath is a cryogenic probe such as the probe 100 shown in Fig. 1. The probe 100 comprises a handle 102, a hollow tubular cannula 106, and a cold tip 108. The cold tip 108 is used to absorb heat from any tissue with which it contacts thereby cooling and potentially freezing the
15 contacted tissue. Thus, in the known probe 100, heat transfer is to occur at the tip 108. However, heat transfer is intended to be limited elsewhere to prevent the unintentionally freezing of tissue contacting the cannula 106.

20

A sterile sheath may be placed over the probe 100 to protect the probe from contamination, and to protect the patient from possible infection. Preferably, the sheath has a thermally conductive region that covers
25 the cold tip 108, and a nonconductive or less conductive region corresponding to the portion of the sheath intended to surround the cannula 106.

In order to insure good thermal conductivity at
30 points where heat transfer is desired, there should be a

snug fit between the sheath and the probe. In order to enhance thermal transfer between the sheath and probe at the desired points a thermal conductive medium (TCM), e.g., thermally conductive grease, may be applied to the
5 inside of the sheath.

Known techniques for applying TCM to the interior of a sheath involve manually applying a TCM to the conductive region, e.g., tip, of the sheath using a
10 hand held wand brush. In the known method, the TCM is first applied to the wand brush and then the brush is inserted into the tip of the sheath transferring the TCM to the inside of the sheath's tip. This method leads to variability in the amount of TCM applied to the sheath
15 and can lead to the problems discussed above associated with TCM lumps and excessive TCM application. In addition to problems relating to variability in TCM application, the known TCM application procedure has the disadvantage of being time consuming to perform.

20

In view of the above discussion, it can be appreciated that there is a need for improved methods and apparatus for applying TCM to specific portions of a sheath. It is desirable that any new TCM application
25 methods produce more reliable and uniform application of TCM to the intended portions of the sheath. It is also desirable that any new TCM application methods reduce the amount of time associated with performing the TCM application process.

30

SUMMARY OF THE INVENTION

The present invention is directed to methods and apparatus for applying a thermal conductive medium
5 (TCM) to the inside of a sheath, e.g., a disposable cryosurgical sheath.

Generally, the goal is to achieve a uniform thin film of TCM between the thermally conductive
10 portions of the probe and sheath when the sheath is covering the probe. Lumps and/or excessive amounts of TCM on the sheath are undesirable since they can interfere with insertion of the probe into the sheath potentially causing rupturing of the sheath during probe
15 insertion. Lumps and/or excessive amounts of TCM can also cause air to be trapped between the tip of the probe and the sheath interfering with thermal transfer, and/or increase thermal transfer along portions of the probe, e.g., the cannula, where heat transfer is not desired.

20

Normally, a TCM is applied to the interior of the sheath prior to packaging. In this manner, the medical technician need only open the sterile sheath and insert the probe prior to use of the probe.

25

In accordance with the invention, a uniform amount of TCM may be applied in an automated manner to the conductive portion of a disposable sheath, using a TCM applicator device of the present invention, to
30 increase conductivity at desired portions of the sheath.

An exemplary TCM application device of the invention includes a TCM pump, tubular shaft, applicator tip, control circuit and a switch. The switch may be manually operated. Alternatively, the switch may be, e.g., a contact switch, that is triggered by placing a sheath over the applicator tip and tubular shaft. In response to activation of the switch, the control circuit beings the pumping of TCM and the applicator shaft and tip are rotated as TCM flows out nozzles in the side of the applicator tip. After TCM is pumped for a fixed amount of time, the pump is stopped by the control circuit while rotation of the applicator shaft and tip is allowed to continue so that the TCM will be spread by the wiping action associated with the rotation. Rotation of the applicator shaft and TIP is stopped after a set amount of time and the sheath is removed. Optionally, the applicator's shaft and tip may be purged of TCM preparing the device for processing of the next sheath.

20

The control circuit may be implemented as a processor controlled by software with set times for starting/stopping the pump and motor being programmed into memory along with said control software. Alternatively the control circuit can be implemented using fixed electrical circuits with the set periods of time being determined by the electrical components selected to implement the control circuit.

25

In one embodiment, the applicator tip is designed with a mushroom shaped top designed to prevent application of TCM to the tip of the sheath. During insertion of the probe TCM from the sidewalls of the sheath will be transferred by the probe to the tip. Accordingly, by limiting and/or preventing application of TCM to the inside tip of the sheath, excessive amounts of TCM at the tip during use are avoided.

Since the amount of TCM applied can be precisely controlled by the time TCM is pumped, application of excessive amounts of TCM can be avoided. In addition, TCM can be applied in a much more uniform manner than can normally be achieved using the known manual TCM application technique.

Because the application process of the invention is performed in an automated manner, it has the additional advantage of normally taking less time than the known manual technique of applying TCM.

Numerous features and advantages of the present invention will be apparent in view of the detailed description set forth below.

25

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a known cryogenic medical probe.

30

Fig. 2 is a diagram of a sheath and an exemplary TCM applicator implemented in accordance with the present invention.

5 Fig. 3 is a diagram of an exemplary TCM applicator tip suitable for use with the TCM applicator illustrated in Fig. 2.

10 Fig. 4 is a flow chart illustrating the steps of a TCM application method of the present invention.

DETAILED DESCRIPTION

15 The present invention is directed to methods and apparatus for applying a thermal conductive medium (TCM), e.g., conductive grease, to portions of the interior of a sheath, e.g., a sheath for a disposable cryosurgical probe. The TCM may be applied in order to increase the thermal conductivity between the disposable
20 sheath and the probe at specific desired locations, e.g., the tip.

Fig. 2 illustrates an exemplary disposable cryosurgical sheath 202 and an exemplary TCM applicator
25 212 implemented in accordance with the present invention. The disposable sheath 202 is shown for purposes of explaining the invention. The sheath 202 includes a tip 204, cannula cover 206 and main body 208. The tip 204 may be made out of a thermally conductive material, e.g.,
30 copper, while the cannula cover 206 and main body 208 may

be made of a flexible insulating material, e.g., a latex material. For purposes of applying TCM to inside portions of the sheath 202, the sheath is placed onto the applicator 212 by moving it in the direction indicated by
5 arrow 210.

The Applicator 212 comprises a tubular applicator tip 214, tubular applicator shaft 220 and main housing 224. The tubular design of the applicator tip
10 214 and applicator shaft 220 provides a hollow channel through the center of the shaft 220 and nozzle 214 through which TCM and/or air can pass.

The tubular applicator tip 214 has a closed tip
15 end 213, an open shaft end 216 and a tubular nozzle portion 215 connecting the tip end and shaft end together. The closed tip end 213 may be mushroom shaped with radial edges protruding over the narrower tubular nozzle portion 215 to prevent application of TCM to the
20 very end to the sheath's tip.

The shaft end 216 of the applicator tip 214 can be attached to the applicator shaft 220 by threads or other non-permanent attachment methods which allow for
25 easy removal, cleaning and/or replacement of the applicator tip 214. Alternatively, the applicator tip 214 can be permanently attached to, and/or integrated with, the applicator shaft 220.

A plurality of nozzles 217 extend axially along the length of the tip's nozzle portion 217. Each nozzle 217 extends through the sidewall of the tip's nozzle portion into the hollow channel extending through the center of the tubular nozzle 214. Nozzles 217 may be implemented as holes in the tip 214. TCM entering the nozzles 214 by way of the tip's hollow channel will be expelled onto portions of the interior surface of the sheath 202. In various implementations nozzle holes having a diameter D in the range between and including 0.142" through 0.144" ($0.142" \leq D \leq 0.144$) were found to be suitable. Nozzles outside the exemplary range may also be used.

When the sheath is placed onto the applicator 212 air can be trapped between the sheath 202 and applicator shaft 220 and/or nozzle 214. In order to remove such air prior to TCM application, the tubular applicator shaft 220 may include an air bleeder hole 218. Air trapped at or near the tip of the sheath 202 during insertion onto the applicator 212 can pass through the nozzles 215 and out through the bleeder hole 218 by way of the hollow channel extending through the center of the applicator shaft and nozzle. Removing the air from the tip portion 214 of the sheath 202 in this manner prior to application of the TCM, facilitates proper positioning of the sheath on the applicator device 212.

The applicator housing 224 comprises a gear and motor assembly 234, a control module 226, and a TCM

dispenser 236. The TCM dispenser includes a TCM storage container 240 which is coupled to a pump 238. When activated pump 238 pumps TCM from the storage container 240 into the shaft's channel and out through the tip's
5 nozzles 217.

The applicator shaft 220 is mounted to the gear and motor assembly 234 which, when activated, causes the shaft 220 and tip 214 mounted thereon to rotate. The
10 control module may include a contact switch 222 which protrudes through the top of the applicator housing 224, and a timing and control circuit 228. Alternatively, instead of a contact switch, a manually operated switch may be used as a start switch. In such an embodiment, an
15 operator manually activates the start switch to begin the TCM application process. The timing and control circuit 228 controls the rotation of the applicator shaft 220 and thus tip 214 by way of a motor control signal supplied to the gear and motor assembly 234. It also controls
20 application of TCM by enabling/disabling a TCM pump 238 included in the dispenser 238 by way of a pump control signal.

Contact switch 222 is activated as a result of
25 contact with the sheath 202 when the sheath is properly placed over the applicator tip and shaft for TCM application. In response to activation of the switch 222, timing and control circuit 228 processes to control motor and pump operation to insure proper application of

TCM as will be discussed further below with reference to Fig. 4.

The design of the TCM applicator tip 214 will
5 now be discussed further with regard to Fig. 3. Fig. 3
illustrates an exemplary tip 214 in detail. As
illustrated, a solid mushroom shaped head 311 is position
at the tip end 213 of the applicator tip 214. The
mushroom shaped head 311 protrudes radially outward
10 beyond the sidewall of the tubular nozzle portion 215 of
the tip 214. Nozzles 217 are uniformly spaced in the
axial direction of the tip 214 by a distance S, e.g.,
.125 inches apart. Nozzles 217 extend along a central
portion of the tip's nozzle region 215. A base 302 is
15 positioned at the shaft end 216 of the tip 302 for
purposes of attachment to the shaft. As discussed above,
the base 302 may be threaded so that it can be screwed to
the shaft 220.

20 From a TCM application standpoint, the
applicator tip 214 can be divided into three regions or
portions, an upper solid tip region 306, a TCM
application region 308 corresponding to the area where
nozzles 217 are located, and a lower tip region 310.

25 Notably, as a result of the applicator tip's
design, application of TCM to the inside tip of the
sheath may be avoided. During use, as a probe is
inserted into the sheath, a small amount of TCM will be
30 scraped from the sidewall of the sheath and forced up

into the tip. Accordingly, by carefully controlling the application of TCM to the sheath's sidewall with the understanding that some of the TCM will be transferred to the inside of the sheath's tip during use, a high degree of uniformity can be achieved in TCM coating while avoiding lumps and/or other insertion problems.

Fig. 4 illustrates an exemplary method 400 for applying TCM to an inside portion of a disposable sheath in accordance with the present invention. The method starts in step 402 with a sheath being selected for TCM application. Then in step 404 the selected sheath is placed over the applicator tip 214 and shaft 220. As the sheath is placed over the shaft 220 it will come into contact with contact switch 222. In response to the start switch 222 being activated, in step 408, the timing and control circuit 228 turns the TCM dispenser pump on. This causes TCM to start traveling up the applicator shaft 220 due to the pumping action. Then, in step 412 the motor 234 is turned on. An optional waiting period, shown as step 410, may be inserted between the time pumping action is started and motor 234 is turned on. Such a waiting period can be useful, e.g., in embodiments where the shaft 220 and applicator tip 214 are purged after each use.

Activation of the motor 234 causes the applicator tip 214 and shaft 220 to rotate as TCM is pushed out the nozzles 217. After a set period of time, in step 414, the timing and control circuit 228 shuts off

the pump 238. Then, in step 416, the control circuit waits for another set period of time before proceeding to step 418 wherein the motor 234 is turned off. Once the motor is turned off, the sheath is removed in step 420.

5

In optional step 422 the timing and control circuit 228 activates the pump to purge the applicator shaft of TCM. This can be done by, e.g., operating the pump 238 to create a vacuum in the shaft 220 to suck out
10 the remaining TCM. After the shaft is purged, the TCM application process stops in step 424 leaving the applicator 212 ready for the next sheath to be processed.

By initiating motor operation after TCM
15 dispensing begins, the risk of damaging the sheath from the rotating action of the applicator tip and shaft is reduced. In addition, by continuing to rotate the applicator tip and shaft after TCM pumping has been stopped serves to distribute the TCM applied near the tip
20 through the wiping action of the rotating tip and applicator shaft.

In one particular exemplary embodiment a specific amount of TCM, e.g., 0.040-0.045 grams, was
25 applied around the inside of the conductive region of disposable sheath 202 to form a thin layer, e.g., 0.0030 inches deep and having a high degree of uniformity.

In the above described manner, the applicator
30 212 of the present invention can be used to spread TCM on

the inner circumference of the conductive region of a disposable sheath evenly, and quickly with far greater accuracy than the known manual application technique. In addition, application of TCM to the tip of the sheath can
5 be avoided and/or minimized allowing the application to occur during probe insertion.

Ten experimental applications were preformed using 80 psi of pressure to pump the TCM, and a 0.143
10 diameter tip. During the tests, the applicator dispensed an average of 0.040 grams of TCM during a 12 second application period, with the range of application amounts being between 0.037-0.043 grams. The resulting thickness of applied TCM to the interior of the sheath at the
15 intended locations varied from a minimum of .0022" to a maximum of .0040". The slight variance between applications during testing shows a high degree of repeatability which is important from a quality control standpoint. Furthermore, using the TCM applicator of the
20 invention produced TCM coatings which were, in most cases, considerably thinner and more uniform than could be achieved using the known manual application technique.

The automated TCM application process described
25 above has the advantage of providing a uniform TCM coating, avoiding lumps, and insuring that TCM application is limited to intended portions of a sheath.

Numerous variations on the above described
30 methods and apparatus are possible without departing from

the scope of the invention. For example, application and removal of sheaths to/from the described TCM applicator device 212 can, and in one embodiment is, automated using a robotic device.